Amendments to the Claim:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-58 (cancelled).

59 (Currently Amended). A kit for inducing an immune response in a human toward an infectious disease to which a human subject and thereby protect said subject against an infectious disease to which a human is susceptible, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, at least one of said immunogens acting to protect against said infectious disease when administered to said subject in suitable amounts at suitable times,

~~said kit comprising at least a single dose of at least two different immunogens, each capable of inducing an immune response against the same infectious disease, said kit providing at least two such immunogens in different amounts,~~

~~wherein at least one of the following conditions holds:~~
~~(1) said kit comprises at least two different capsular pneumococcus immunogens, each conjugated to at least one carrier protein,~~
~~(2) said kit comprises at least two different capsular meningococcus immunogens, each conjugated to at least one carrier protein,~~
~~(3) said kit comprises at least two different acellular pertussis immunogens, or~~
~~(4) said kit comprises at least two different purified viral capsid immunogens,~~

~~wherein the kit is manufactured by a process comprising~~

~~accepting at least one lot of at least one immunogen for use in production of the kit after determining a dose of at least one said immunogen is safe according to a method of~~

~~a) comparing the incidence, prevalence, frequency or severity of a chronic immune-mediated disorder, or the level of a marker of such a disorder, in a treatment group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a control group of humans~~
~~and/or~~

~~b) comparing the risk of a chronic immune-mediated disorder in a first group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a second group of humans, said first group of humans having been immunized with one or more doses of said immunogen according to a first screened immunization schedule, and the second group of humans having been immunized with one or more doses of said immunogen according to a second screened immunization schedule, each group of humans having been immunized according to a different immunization schedule,~~

~~said immunization of (a) or (b) inducing an immune response, comprising production of antibodies or activation of T-cells, in at least one such group~~

said kit comprising labeling containing information

(a) that the kit can be used to reduce the incidence of a chronic immune-mediated disorder in a mammal, and providing instructions for the prophylactic or therapeutic

use of said immunogens to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, said instructions stating that one or more doses should be administered according to an immunization schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder,

or

(b) regarding data from any clinical trial of the effect of any of said immunogens, when administered according to a specific immunization schedule, compared to a control group, on the incidence of a chronic immune-mediated disorder.

60 (previously presented). The kit of claim 59 where (a) applies.

61 (previously presented). The kit of claim 59 where (b) applies.

62-317 (Cancelled).

318 (Currently Amended). A method of making a pharmaceutically acceptable kit for use, prophylactically or therapeutically, in the immunization of a mammalian subject against at least one infectious disease, which comprises

(a) ~~providing at least one immunogen which is protective, after one or more doses, against at least one infectious disease,~~

~~(b)~~

~~(1)~~ comparing the incidence, prevalence, or frequency or severity of a chronic immune-mediated disorder, ~~or the level of a marker of such a disorder,~~ in a treatment group of humans immunized according to an immunization schedule with one or more doses of ~~said~~ at least one immunogen, with that in a control group of humans, ~~and/or~~

~~(2) comparing the risk of a chronic immune-mediated disorder in a first group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a second group of humans, said first group of humans having been immunized with one or more doses of said immunogen according to a first screened immunization schedule, and the second group of humans having been immunized with one or more doses of said immunogen according to a second screened immunization schedule, each group of humans having been immunized according to a different immunization schedule,~~

said immunization of ~~(1) or (2)~~ (a) inducing an immune response, comprising production of antibodies or activation of T-cells, in at least one such group,

(b) selecting at least one immunogen so compared for inclusion in said kit, and providing said at least one immunogen,

wherein said immunogen is protective, when administered according to a suitable immunization schedule, against at least one infectious disease,

(c) providing at least one container, and introducing one or more doses of one or more tested immunogens into said container, and

(d) assembling the container or containers comprising said immunogens into a kit.

319 (Previously Presented). The method of claim 318, further comprising labeling said container or containers, or said kit.

320 (Previously Presented). The method of claim 319, said labeling providing instructions for the use of said kit to immunize a mammalian subject against at least one

infectious disease.

321 (Previously Presented). The method of claim 320, said testing including testing of said immunogen when used according to said instructions.

322 (Currently Amended). A method of making a pharmaceutically acceptable immunogenic agent comprising pharmaceutically acceptable amounts of each of one or more immunogens, said immunogens being protective, after one or more doses, against at least one infectious disease, which comprises

(a) ~~providing at least one immunogen which is protective, after one or more doses, against at least one infectious disease,~~

~~(b)~~

~~(1)~~ comparing the incidence, prevalence, or frequency ~~or severity~~ of a chronic immune-mediated disorder, ~~or the level of a marker of such a disorder,~~ in a treatment group of humans immunized according to an immunization schedule with one or more doses of ~~said~~ at least one immunogen, with that in a control group of humans, ~~and/or~~

~~(2) comparing the risk of a chronic immune-mediated disorder in a first group of humans immunized according to an immunization schedule with one or more doses of said immunogen, with that in a second group of humans, said first group of humans having been immunized with one or more doses of said immunogen according to a first screened immunization schedule, and the second group of humans having been immunized with one or more doses of said immunogen according to a second screened immunization schedule, each group of humans having been immunized according to a different immunization~~

~~schedule,~~

said immunization of ~~(1) or (2)~~ (a) inducing an immune response, comprising production of antibodies or activation of T-cells, in at least one such group,

(b) selecting at least one immunogen so compared for inclusion in said kit, and comprising said immunogen, wherein said immunogen is protective when administered according to a suitable immunization schedule, against at least one infectious disease,

and

(c) packaging at least one dose of said immunogen into said immunogenic agent.

323-324 (Cancelled).

325 (New). The method of claim 318 wherein, in step (a), incidence is compared.

326 (New). The method of claim 318 wherein at least one of said immunogens of (a) is an immunogen selected from the group consisting of anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

327 (New). The method of claim 318 wherein at least one of

said immunogens of (a) is an immunogen selected from the group consisting of diphtheria, tetanus, pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens.

328 (New). The method of claim 318 wherein the infectious disease protected against is one for which an immunogen selected from the group consisting of diphtheria, tetanus, pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens is protective.

329 (New). The method of claim 318 wherein the chronic immune-mediated disorder is diabetes.

330 (New). The method of claim 318 wherein the chronic immune-mediated disorder is diabetes and said immunogen is given starting before at least 60 weeks of age.

331 (New). The method of claim 329 wherein said immunization schedule begins before 42 days of age.

332 (New). The method of claim 318 wherein, in step (a), the immunization schedule for the control group differs from that for the treatment group at least by (i) lacking at least one immunogenic agent/adjuvant provided in the treatment schedule; (ii) including at least one immunogenic agent/adjuvant provided in the treatment schedule.

333 (New). The method of claim 318 wherein the kit comprises at least one pediatric immunogen and at least one non-pediatric immunogen.

334 (New). The method of claim 318 wherein the chronic immune-mediated disorder is diabetes.

335 (New). The method of claim 332 wherein, in step (a), the

immunization schedule for the control group differs from that for the treatment group at least by including different immunogens associated with the same infectious disease pathogen.

336 (New). The method of claim 318, further comprising testing one or more lots of said kit for the effect of at least one immunogen of said kit on the incidence, prevalence, or frequency of a chronic immune-mediated disorder.

337 (New). The method of claim 318 wherein the incidence of at least one chronic immune-mediated disorder at least one year after immunization is compared.

338 (New). The method of claim 318 wherein the incidence of diabetes at least one year after immunization is compared.

339 (New). The method of claim 318 wherein the subjects were randomized into the treatment group and the control group.

340 (New). The method of claim 330 wherein the subjects were randomized into the treatment group and the control group.

341 (New). The method of claim 338 wherein the subjects were randomized into the treatment group and the control group.